

HEPATITIS C TREATMENT Prior Authorization Request Form

For members to receive coverage for Hepatitis C Treatment, it will be necessary for the prescriber to complete and fax this prior authorization request to Change Healthcare. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information. For questions, please contact the Change Healthcare Help Desk at 1-844-679-5363.

Submit request via: Fax: 1-844-679-5366

Prescribing physician:

Name: _____
Physician NPI: _____
Phone#: _____
Fax#: _____
Address: _____
Contact Person at Office: _____

Beneficiary:

Name: _____
Medicaid ID#: _____
Patient's Phone#: _____
Date of Birth: _____ Sex: _____
Pharmacy Name: _____
Pharmacy NPI: _____
Pharmacy Phone: _____ Pharmacy Fax: _____

Hepatitis C treatment PA requests will be approved for members who meet the following guidelines. This PA form will cover up to twelve weeks of therapy. This form outlines the various regimens and clinical situations for which they will be considered medically necessary by Vermont Medicaid, as well as the required supporting documentation. The PA must be approved prior to the 1st dose. Documentation of adherence (viral load changes or progress notes with a documented compliance discussion with details on compliance to date) will be required for continuation of therapy beyond 12 weeks & must be submitted with the PA request prior to completing the third month of therapy.

Most patients will qualify for the Simplified Treatment outlined on this page. If they do not, additional options are on the subsequent pages. Information about simplified treatment at: <https://www.hcvguidelines.org/treatment-naive/simplified-treatment>.

WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT	WHO IS NOT ELIGIBLE FOR SIMPLIFIED TREATMENT
<p>Adults (18+ years of age) with chronic hepatitis C (any genotype) who (please check appropriate boxes):</p> <p><input type="checkbox"/> Do NOT have cirrhosis by lab or clinical exam</p> <p><input type="checkbox"/> Have NOT been treated in the past</p> <p><input type="checkbox"/> Are NOT pregnant</p> <p><input type="checkbox"/> HIV negative</p> <p><input type="checkbox"/> Hepatitis B Surface Antigen negative</p> <p><input type="checkbox"/> NO known or suspected hepatocellular carcinoma</p> <p><input type="checkbox"/> NO prior liver transplantation</p>	<ul style="list-style-type: none"> Prior hepatitis C treatment Cirrhosis HIV or Hepatitis B Surface Antigen positive Current pregnancy Known or suspected hepatocellular carcinoma Prior liver transplantation <p><u>IF NOT ELIGIBLE SEE OPTIONS ON FOLLOWING PAGES</u></p>

Preferred Regimens (check one)

- Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks)
- sofosbuvir/velpatasvir 400/100 mg daily for 84 days (12 weeks)

Required Information/Labs: copies MUST be submitted (done within 6 months of PA request)

Calculated FIB-4 Score: _____ (<https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4>) (FIB 4 = (Age x AST) / (Platelet count x √ALT))

CBC: fibrosis score (if known, optional): _____

Hepatic function panel: albumin, total and direct bilirubin, ALT, AST:

Calculated glomerular filtration rate: eGFR: _____

Quantitative HCV RNA viral load: _____

HCV Genotype: please circle 1a 1b 2 3 4 5 6 mixed date: _____

HIV antigen/antibody test:

Hepatitis B surface antigen:

Within 60 days of request in women of childbearing age: serum pregnancy test:

Pre-treatment Assessment/On-Treatment Monitoring and Follow-up Recommendations Available at:

<https://www.hcvguidelines.org/treatment-naive/simplified-treatment>

Providers are urged to check an online drug interaction site such as: <https://www.hep-druginteractions.org/checker>

FOR PATIENTS WHO DO NOT MEET CRITERIA FOR SIMPLIFIED TREATMENT, SEE BELOW**Please attach documentation of the following:**

<input type="checkbox"/> Quantitative HCV RNA viral load within the last 6 months* <input type="checkbox"/> Child-Turcotte-Pugh (CTP) Score: _____ Date: _____ <input type="checkbox"/> Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. <input type="checkbox"/> Within 60 days of request in women of childbearing age: pregnancy test*	<input type="checkbox"/> HCV Genotype verified by lab * Genotype: (circle) 1a 1b 2 3 4 5 6 <u>Labs below done within the last 6 months</u> <input type="checkbox"/> Fibrosis score*: _____ Date: _____ method: _____ <input type="checkbox"/> CBC* <input type="checkbox"/> Hepatic function panel*: albumin, total and direct bilirubin, ALT, AST <input type="checkbox"/> Calculated glomerular filtration rate: eGFR* _____ <input type="checkbox"/> Quantitative HCV RNA viral load* _____ <input type="checkbox"/> HIV antigen/antibody test* _____ <input type="checkbox"/> Hepatitis B surface antigen* _____
<input type="checkbox"/> Prescriber is, or has consulted with, a gastroenterologist, hepatologist, ID specialist or other Hepatitis specialist. Consult must be within the past year with documentation of recommended regimen.*	<input type="checkbox"/> Provider certifies they have checked an up-to-date drug interaction list or on-line list such as: https://www.hep-druginteractions.org/checker .

PEDIATRIC NOTE: FDA approved pediatric formulations of direct acting antivirals (DAA) and DAA approved for pediatric use will be approved for those under the age of eighteen when used in accordance with current AASLD guidelines including for indication and age. Prior authorization is still required prior to the first dose and for treatment naive children when used in accordance with the table below.

GT	Age (years)	Weight (kg)	Drug/Dose	Weeks
1,4,5,6	3-5	<17	Harvoni 33.75/150 mg pellet pack	12
		17 to <35	Harvoni 45/200 mg pellet pack or tablet	12
		≥35	Harvoni 90/400 mg tablet	12
Any	≥6	≥17 to < 30	Epclusa 200/50 mg tablet	12
		≥30	sofosbuvir/velpatasvir 400/100 mg tablet	12
Any	≥12	≥45	Mavyret 100/40 mg tablets -OR-	8
			sofosbuvir/velpatasvir 400/100 mg tablet	12

NOTE: Adult Guidelines have changed substantially; most recommendations are largely genotype non-specific; exceptions are noted in red

ADULT: Treatment naïve**No cirrhosis**

- Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended)
- sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

Compensated cirrhosis, HIV negative

- Mavyret 100/40 mg, three (3) tablets daily for 8 weeks
- sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

Compensated cirrhosis, HIV positive

- Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

ADULT: Treatment experienced (with or without compensated cirrhosis)**Sofosbuvir-based regimen**

- Mavyret 100/40 mg, three (3) tablets daily for 16 weeks

NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)

- Vosevi 400/100/100 mg, one tablet daily for 12 weeks

Mavyret

- Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight based RBV)

Vosevi or sofosbuvir + Mavyret

- Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 24 weeks

GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)

- Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 12 weeks

ADULT: Re-infection of Allograft Liver after Transplant**DAA-treatment naïve, no decompensated cirrhosis**

- Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

DAA-treatment experienced, no decompensated cirrhosis

- Vosevi 400/100/100 mg, one tablet daily for 12 weeks

IF multiple negative baseline characteristics, consider

- Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks

Treatment naïve, decompensated cirrhosis

- sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks

Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)

- sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks

ADULT: Decompensated Cirrhosis**No prior sofosbuvir or NS5A failure**

- sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis)
- sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)

Prior sofosbuvir or NS5A failure

- sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

Other Treatment Regimen**Genotype, treatment history, and extent of liver disease:**

Drug names, doses and durations:

Clinical rationale for selecting regimens other than those outlined above:

Abbreviations RBV=ribavirin; PI=protease inhibitor; DAA=direct acting antiviral

low dose ribavirin = 600 mg/day and increase as tolerated

For ANY regimen that includes ribavirin

- For women of childbearing potential** (and male patients with female partners of childbearing potential):
 - Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping
 - Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping
 - Verification that monthly pregnancy tests will be performed throughout treatment

For ribavirin-ineligible (Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced**

- History of severe or unstable cardiac disease
- Pregnant women and men with pregnant partners
- Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- Hypersensitivity to ribavirin
- Baseline platelet count <70,000 cells/mm³
- ANC <1500 cells/mm³
- Hb <12 gm/dl in women or <13 g/dl in men
- Other: _____

By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in your medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

Provider Signature: _____ **Date of Submission:** _____

***MUST MATCH PROVIDER LISTED ABOVE**